UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

ERIC ANTHONY NEPUTE,
individually, and as
Owner of Quickwork LLC; and

QUICKWORK LLC,
a limited liability company,
also d/b/a WELLNESS WARRIOR,

Defendants.

Case No.: 4:21-CV-00437

REPLY MEMORANDUM IN SUPPORT OF THE UNITED STATES' MOTION TO EXCLUDE DEFENDANTS' EXPERTS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

I. INTRODUCTION

Defendants' arguments in favor of admissibility of their proffered expert testimony lack merit. *First*, expert testimony in this case is directed to a narrow issue: whether sufficient evidence exists to satisfy the relevant scientific community that Vitamin D and Zinc can prevent and treat COVID-19. Neither Dr. Parks nor Nepute are qualified to answer this question. Dr. Parks has not conducted formal research since 2000, and even then, she did not research whether compounds can treat or prevent illness. Nepute is not a medical doctor and does not evaluate clinical data in accordance with the relevant scientific community. *Second*, while Defendants disclaimed that Drs. Parks and Holick will testify about a reasonable consumer's interpretation of Nepute's statements, their testimony about how they interpret those statements should be excluded as unhelpful to the jury, which is fully capable of assessing whether Nepute claimed that Vitamin D or Zinc could treat or prevent COVID. *Third*, Defendants' argument that Dr. Parks and Nepute have adequately articulated their methodology attacks a strawman; the United States is not arguing that non-randomized controlled trial ("RCT") evidence should never be considered, but rather that Defendants' experts failed to explain how they weighed conflicting results from different study designs. Such an explanation is especially important because Nepute purported to review over 400 studies. Nevertheless, that explanation has not been supplied. Therefore, the United States' motion to exclude Defendants' expert testimony should be granted in its entirety.

II. ARGUMENT

A. Defendants' Attempts to Bolster Dr. Parks' and Nepute's Qualifications Fail

Defendants argue that Dr. Parks and Nepute have sufficient education, training, and experience to testify that Vitamin D and Zinc can serve as effective COVID-19 therapeutics. *See* ECF No. 100 ("Opp.") at 2-9. They do not.

1. Dr. Parks Is Unqualified To Testify To The Clinical Benefits Of Zinc

To support Dr. Parks' qualifications, Defendants rely on two grounds: her 1999 doctorate, and her more-recent experience as a science educator. *See* Opp. at 2-3. Neither is sufficient to qualify her to testify as to the clinical benefits of Zinc here.

Dr. Parks' academic experience is outdated and not directly relevant to the issues at hand. Dr. Parks' doctorate is over twenty years old, and she has not performed any peer-reviewed research since 2000. ECF No. 79-2 (Parks Tr.) at 30:20-23. Even when she was academically active, she did not perform any research into whether Zinc or any other compound could prevent or treat disease—the core issue in this case. *See* ECF No. 79 ("Br.") at 6-7. Her two decades-old research in an adjacent field does not qualify her to testify regarding the clinical benefits of Zinc. *See Shipp v. Murphy*, 9 F.4th 694, 701 (8th Cir. 2021) (excluding testimony from a nurse practitioner "on a physician's standard of care" and explaining that the "'area of the witness's competence [must] match the subject matter of the witness's testimony'" (quoting *Robinson v. GEICO Gen Ins.*, 447 F.3d 1096, 1101 (8th Cir. 2006) (alterations omitted)); *McCabe v. Macaulay*, No. 05-CV-73, 2008 WL 2980009, at *5 (N.D. Iowa Apr. 29, 2008) (holding that an expert's testimony was "outdated, stale and inadmissible" where he left the relevant field in 1991 and had "not received any formal training or continuing education" since 1989); *see also Bone Shirt v. Hazeltine*, 461 F.3d 1011, 1026 (8th Cir. 2006) (Gruender, J., concurring) ("Science evolves, and scientific methods that were once considered unassailable truths have been discarded over time. Unreliable testimony based upon those outdated theories and methods must be discarded as well, lest scientific stare decisis ensure that such theories survive only in court.")

Dr. Parks' teaching experience is similarly insufficient to qualify her here. Dr. Parks' work as a high school science educator simply does not encompass performing or evaluating original research to determine whether compounds can prevent or treat disease. Furthermore, Defendants'

characterization of Dr. Parks' work for her wholly owned consulting firm, New Health Paradigms, glosses over the fact that any explanations of "complex deep science" she provides are subjectively filtered through "what [she] feel[s] is [her] area of expertise." ECF. No. 100-2 (Parks Tr.) at 38:21-23. Dr. Parks' own evaluation of her expertise is not an objective assessment of whether she is qualified to offer an expert opinion about the clinical therapeutic effects of Zinc.

Defendants' authority is not to the contrary. Citing *Obesity Research Institute v. Fiber Research International*, No. 15-CV-595, 2017 WL 1166307 (S.D. Cal. Mar. 29, 2017), Defendants argue that Dr. Parks is qualified to testify regarding her interpretation of clinical science even though she is not a medical doctor and has not performed any clinical trials. While a non-medical doctor who has not performed clinical trials might qualify to testify regarding the effectiveness of a compound to prevent or treat disease, that person would need other sufficient qualifications. *Obesity Research* illustrates this point. There, the Court denied a motion to exclude an expert who "[f]or the past 30 years" had "analyzed biological molecules, developed and validated assays on the quality of active pharmaceutical ingredients, and compared chemical qualities of drugs;" and who "regularly compare[d] drug products in her work." *Id.* at *2 (alterations and internal quotation marks omitted). The thirty years of relevant academic and practical experience possessed by the *Obesity Research* expert far exceeds Dr. Parks' decades-ago academic experience and unrelated teaching experience.

Defendants' other authorities further support the United States' contention that a qualified expert needs relevant and up-to-date experience. *See Hogland v. Town & Country Grocer of Fredericktown Missouri, Inc.*, No. 3:14-CV-273, 2015 WL 3843674, at *28-*30 (E.D. Ark. Jun. 22, 2015) (excluding opinion of a "vocational and rehabilitation expert" who was "not a medical doctor" to the extent that opinion was not supported by "medical evidence in the record"); *In re*

Zurn Pex Plumbing Prod. Liab. Litig., 267 F.R.D. 549, 556 (D. Minn. 2010) (denying a motion to exclude an experienced statistician at the class certification stage whose qualifications to conduct the scientific analysis forming the basis of his opinion were not contested), *aff'd* 644 F.3d 604 (8th Cir. 2011); *Union Cnty., Iowa v. Piper Jaffray & Co.*, No. 4:06-CV-374, 2010 WL 11679204, at *1, *3 (S.D. Iowa Dec. 5, 2010) (finding a certified public accountant qualified to render an opinion on damages based on their "extensive education and experience in the area" including accreditations, publications, prior testimony, and history of lecturing on damages); *see also Lewert v. Boiron, Inc.*, 212 F. Supp. 3d 917, 925 (C.D. Cal. 2016) (rejecting a motion to exclude expert's opinion about a flu product's active ingredient and clinical support for advertising claims where the expert has "years of experience in laboratory research and scientific publication, ha[d] served on the scientific advisory board of three different drug development companies, assisting in pre-clinical experimental design and clinical trial data analyses, and [taught] students how to evaluate clinical studies" and the movants "offered no reason for why [the expert was] objectively unqualified to opine" on the issue), *aff'd* 742 F. App'x 282 (9th Cir. 2018); *In re Lipitor*, No. 2:14-MN-2502, 2016 WL 2940784, at *3 (D.S.C. May 6, 2016) (explaining that "a two-year fellowship over 30 years ago, standing alone, does not qualify someone as an expert" in interpreting scientific data, then finding the expert qualified based on, among other things, having published literature "criticizing the original analyses of clinical trials and re-analyzing data from clinical trials").

Because Dr. Parks lacks the qualifications that the experts in these cases were found to have had, her testimony should be excluded.

2. Nepute Is Unqualified To Testify To The Clinical Benefits Of Vitamin D Or Zinc

Defendants also contend that Nepute is qualified by his "education, training, and experience" to testify as an expert on the clinical benefits of Vitamin D and Zinc. Opp. at 7.

Nepute's chiropractic experience is insufficient to permit him to provide expert testimony regarding the clinical benefits of Vitamin D or Zinc to prevent or treat COVID-19.[1] As noted previously—and not contested by Defendants—Nepute does not practice medicine and cannot do so without violating Missouri state law. *See* Br. at 8. Nor do Defendants contest that Nepute's practice primarily sees patients for neuromusculoskeletal issues, fatigue, and nutritional care; it does not primarily see patients for the use of compounds to prevent or treat disease. *Id.*

The nature of Nepute's practice is critical to assessing his qualifications here. As previously noted, the claims in this case—that Nepute deceptively marketed his products to prevent and treat COVID-19 in violation of the FTC Act and COVID-19 Act—require the United States to show that Nepute lacked evidence sufficient to satisfy the relevant scientific community. *See* Br. at 2-3. The relevant scientific community to assess these claims is the community that evaluates existing data to determine whether compounds can prevent or treat disease. But, as Defendants recognize, Nepute's approach is not purely to evaluate the effectiveness of a compound; rather, he "look[s] at risk verse (sic) benefit" in reaching conclusions regarding how to treat his patients. ECF No. 79-7 (Nepute Tr.) at 47:21-22; *id.* at 53:14-17 ("Everything to me, goes back to risk verse (sic) benefit."); *see also* Opp. at 8-9 (asserting Nepute is "qualif[ied] to testify both to the benefits of vitamin D and zinc as well as the absence of adverse side-effects"). For example, in Nepute's view, Vitamin D supplementation would be appropriate even if "somebody is Vitamin D sufficient,"

[1] The United States does not dispute that, as a fact witness, Nepute can supply what he claims is "the scientific basis upon which he made the alleged misstatements." Opp. at 6. That testimony goes to whether Defendants had sufficient "substantiation for [their] representation[s] prior to making [them] in an advertisement." *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 298 (D. Mass. 2008), *aff'd,* 624 F.3d 1 (1st Cir. 2010). But Nepute is not qualified to testify as an expert on whether that evidence is sufficient to satisfy the relevant scientific community that Vitamin D and Zinc can treat and/or prevent COVID-19. *Cf. In re Zurn Pex Plumbing Prod. Liab. Litig.*, 644 F.3d 604, 613 (8th Cir. 2011) ("The main purpose of *Daubert* exclusion is to protect juries from being swayed by dubious scientific testimony.")

because "the chances of having a negative effect [from supplementation] are very slim." Reply Ex. 1 at 148:17-20. This risk/benefit analysis—essentially deciding to recommend supplements with the rationale that they will probably not hurt the patient—is not the appropriate analysis here; the United States is alleging that Nepute marketed his supplements as preventing or treating COVID-19 without sufficient evidence to do so, not that he deceptively marketed them as having a positive risk/benefit ratio.

Viewed through this lens, Nepute's education and training are also insufficient to qualify him to testify as an expert. While Nepute has obtained a chiropractic degree and post-graduate certifications, that education and training were in support of his chiropractic practice, which, as discussed above, is not the framework that the relevant scientific community would use to evaluate his claims concerning the prevention or treatment of COVID-19. Moreover, he obtained at least some of his post-graduate certifications to "add[] to [his] knowledge base of how [his practice] take[s] care of [its] patient[s]"—that is, through the application of risk/benefit based care. *Id.* at 37:7-12 (Quantum University); *see also id.* at 42:7-10 (explaining a certified nutritional specialist certification is "inferior to the Doctorate of Chiropractic" and "just more knowledge-based").

Defendants also attempt to bolster Nepute's qualifications by pointing to the literature regarding Vitamin D and Zinc as therapeutics for COVID-19. *See* Opp. at 8. But that is the very literature on which Nepute relies to form his opinions. His qualifications to review and interpret that literature is what is at issue here; the fact that he reviewed that literature, or that it exists, does not qualify him to testify him as an expert. Nor are his qualifications commensurate with the experts in the cases that Defendants cite. *See supra* at 3-4. He should therefore be excluded.

B. Dr. Parks and Dr. Holick Should Not Be Permitted To Testify Regarding Their Interpretations of Nepute's Statements

In their opposition, Defendants represent that Drs. Parks and Holick will not offer opinions regarding how consumers may interpret Nepute's statements. *See* Opp. at 15. However, both experts do intend to testify that they were personally unable to "locate instances of Defendants' alleged misstatements as characterized by the Complaint." *Id*. Such personal interpretations of Nepute's statements, however, are "no better than another person's opinion." *See FTC v. Washington Data Res.*, No. 8:09-CV-2309, 2011 WL 2669661, at *2 (M.D. Fla. July 7, 2011). Without relevant expertise, *see* Br. at 9-10, Drs. Parks and Holick are no better equipped than the Court or jury to assess whether Nepute's statements convey the "net impression" that Vitamin D or Zinc can prevent or treat COVID-19. *See, e.g., FTC v. Fleetcor Tech., Inc.*, No. 1:19-CV-5727, 2022 WL 3273286, at *6 (N.D. Ga. Aug. 9, 2022). This testimony should therefore be excluded as unhelpful to the jury. *See* Fed. R. Evid. 702.

C. Dr. Parks and Nepute Have Not Articulated A Reliable Methodology to Support Their Opinions That Zinc Can Treat Or Prevent COVID-19

Finally, Defendants' justifications for Dr. Parks' and Nepute's methodologies supporting their opinions that Zinc can prevent or treat COVID-19 lack merit. *See* Opp. at 9-15.

1. The Problems Inherent In Defendants' Methodology Do Not Require The Court To First Find That Only RCTs Constitute Competent and Reliable Scientific Evidence

Defendants first contend that, to disqualify their experts, the Court must first find that only RCTs can constitute competent and reliable scientific evidence. *See* Opp. at 9-11. This misstates the United States' position. As explained, "the methodological flaw in [Dr. Park's and Nepute's] expert opinions is *not* that they rely on observational and *in vitro* studies [in addition to RCTs] in reaching their conclusions." Br. at 15. Rather, it is their failure to adequately articulate *how* they weighed conflicting results between RCTs and other types of scientific evidence and determined

that there was adequate evidence of causation versus correlation. *See* Br. at 13-15. Put another way, even if the Court were to accept that observational and *in vitro* studies could be sufficient to infer causation—*i.e.,* that Vitamin D or Zinc treats or prevents COVID-19—the Court would *then* need a reliable methodology to reconcile different study designs that reached different or conflicting results. Defendants' experts have failed to explain how the Court could reconcile those differences.

Defendants' discussion of *In re Bair Hugger Forced Air Warming Devices Prod. Liab. Litig.*, 9 F.4th 768 (8th Cir. 2021) also misses this point. *See* Opp. at 11-12. While the Eighth Circuit noted that observational studies could be sufficient to show that an intervention causes a health outcome in certain circumstances, the Court further held that testimony is properly excluded where experts fail to explain how to account for potentially conflicting data. As the Eighth Circuit explained, "[n]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Bair Hugger,* 9 F.4th at 782 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Defendants' references to the FTC Dietary Supplements Advertising Guidelines and to differing regulatory frameworks for dietary supplement and drug products, *see* Opp. at 10-11, are inapposite for the same reason. Even if the dietary supplement regulatory framework could allow the use of non-RCT evidence to substantiate health claims, a reliable methodology still requires an adequate articulation of how the expert weighed conflicting evidence from different study types.[2]

[2] The United States also notes that, because Defendants intended their products to be used in the treatment and prevention of COVID-19, they are "drugs" within the meaning of the FTC Act. *See* 15 U.S.C. § 55(c). In any event, the FTC Advertising Guide also urges supplement manufacturers to consider study quality in assessing the level of substantiation for health claims, *see* ECF No. 100-7 at 10; and explains that "well controlled human clinical studies are the most reliable form of evidence," *id.* at 14.

2. Defendants Have Failed To Adequately Articulate Their Methodology For Assessing Different Study Designs

Defendants' attempts to address the actual flaws in their expert opinions fail. In their opposition, Defendants characterize Dr. Parks' and Nepute's methodologies in essentially the same way: they first reviewed *in vitro* studies that discuss biological mechanisms for how Zinc might impact the immune system; and then reviewed some observational studies and RCTs relating to Zinc's ability to prevent or treat COVID-19. What they have not articulated—in reports, depositions, or in the opposition—is an explanation for *how* Dr. Parks and Nepute weighed conflicting studies or took into account different study types, again, for the critical purpose of bridging the gap between correlation and causation. This differentiates these experts' reports from that of Dr. Dubberke, who *did* explain how he assessed different study designs. *See* ECF No. 79-1 at ¶¶ 15-28. And it renders it impossible for the Court to assess the reliability of their methodology. *See Bair Hugger*, 9 F.4th at 777-78.

Many investigators have conducted different types of studies to consider whether Vitamin D or Zinc might *potentially* serve as an effective COVID-19 therapeutic. Nepute professes to have reviewed over 400 Vitamin D and Zinc studies in reaching his opinions. *See* Opp. at 13. The extent of the available research makes it easy for an unscrupulous expert to cherry-pick favorable studies. *But see Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005) (excluding experts who "ignored or discounted without explanation the contrary epidemiological studies"); *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007) (excluding expert who "cherry-pick[ed] observational studies that support his conclusion and reject[ed] or ignore[ed] the great weight of the evidence that contradicts his conclusion"). The aggregate quantity of available research makes it all the more important that the expert articulate

a specific methodology for weighing conflicting results between different studies and study designs, so as to not mislead the jury.

Despite this heightened need, Defendants' experts failed to articulate a clear methodology that would assist the factfinder tasked with assessing the scientific evidence. With respect to the illustrative Thomas study—an RCT concluding that Zinc supplementation did not improve COVID-19 outcomes for certain patients—Defendants argue that Dr. Parks discounted it because it tested the therapeutic effectiveness of Zinc only *after infection*. Opp. at 14. Even if true, this explanation falls short in explaining why Dr. Parks discounted this study when formulating her opinion that Zinc can *improve outcomes* in COVID-19 patients (as opposed to preventing COVID-19). More generally, Dr. Parks did not explain: (i) what factors she applied in reviewing other RCTs; (ii) how she identified or assessed any flaws with any of the observational or *in vitro* studies on which she relied; nor (iii) how she handled conflicting results. Nor has Nepute. An adequate articulation requires an explanation for why studies showing unfavorable results are being discounted or disregarded. *See Bair Hugger*, 9 F.4th at 779 (explaining that an expert must "do[] the work 'to bridge the gap between association and causation'"). Dr. Parks and Nepute did not provide that explanation.

Defendants' apparent contention that that they discounted RCTs because of what they term to be their "inherent shortcomings" does not excuse their failure to articulate their methodology. *See* Opp. at 14. While Defendants suggest that RCTs are neither feasible nor ethical in some circumstances, this does not change the fact that RCTs were undisputedly conducted. Defendants' experts should have articulated how they considered these conflicting RCTs.

Finally, Defendants appear to argue that COVID-19's status as a novel disease excuses their failure to articulate their methodology. *See* Opp. at 11. This throws the baby out with the

bathwater. During a novel pandemic, it might make sense to investigate potential therapeutics using *in vitro* data and extrapolations from other viruses. The United States' expert suggested the same. *See* ECF No. 79-1 at ¶ 36. But the fact that COVID-19 is a novel disease does not excuse scientists and practitioners from adhering to the well-established methodologies for experimenting with, evaluating, and determining the effectiveness of various drugs at preventing or treating COVID-19. It certainly does not mean that "anything goes" in terms of advertising purported treatments and cures. In order to claim that their products prevent and treat COVID-19, Defendants need competent and reliable scientific evidence. Dr. Parks and Nepute failed to explain why they disregarded the unfavorable scientific evidence in reaching their conclusions, so they should be excluded from testifying.

III. CONCLUSION

For the foregoing reasons, and for the reasons set forth in the Motion to Exclude Defendants' Experts and accompanying Memorandum of Law, ECF Nos. 78-79, the United States respectfully asks this Court to exclude Dr. Parks' testimony and Nepute's testimony entirely, and to exclude Dr. Holick from testifying regarding his interpretation of Nepute's statements.

Dated: October 7, 2022

Respectfully submitted,

FOR THE UNITED STATES OF AMERICA:

SAYLER FLEMING
United States Attorney
Eastern District of Missouri

SUZANNE J. MOORE MO#45321
Assistant United States Attorney
Thomas F. Eagleton U.S. Courthouse
111 South Tenth Street, 20th Floor
St. Louis, MO 63102

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director
Consumer Protection Branch

Tel: (314)539-2200
Fax: (314)539-2196
Email: suzanne.moore@usdoj.gov

LISA K. HSIAO
Assistant Director
Consumer Protection Branch

/s/ Zachary L. Cowan
BRANDON ROBERS 1112150055(MD)
BEN CORNFELD 1048311(DC)
ZACHARY COWAN 53432(NC)
Trial Attorneys
Consumer Protection Branch
U.S. Department of Justice
Civil Division
450 5th Street, N.W.
Washington, D.C. 20530
Tel: 202-598-7276 (Cornfeld)
Tel: 202-305-2023 (Robers)
Tel: 202-598-7566 (Cowan)
Fax: 202-514-8742
Benjamin.A.Cornfeld2@usdoj.gov
Brandon.Robers@usdoj.gov
Zachary.L.Cowan@usdoj.gov

Of Counsel:

KRISTIN M. WILLIAMS
MARY L. JOHNSON
Attorneys
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Mailstop CC-10528
Washington, D.C. 20850
Tel: 202-326-2619 (K. Williams)
Tel: 202-326-3115 (Johnson)
Fax: 202-326-3259
Kwilliams2@ftc.gov
Mjohnson1@ftc.gov